HYPERTENSION THERAPIES AND RENAL DENERVATION

Tuesday, October, 13, 2015, 4:00 PM-6:00 PM

Abstract nos: 764 - 774

TCT-764

Bipolar Radiofrequency Renal Denervation with the Vessix Catheter in Patients with Resistant Hypertension: 2-year Results from the REDUCE-HTN Trial

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BACKGROUND The Vessix Renal Denervation System (Boston Scientific, Marlborough, MA) consists of an over-the-wire low-pressure balloon catheter with an array of bipolar radiofrequency electrodes. Primary endpoint results of the REDUCE-HTN trial showed significant blood pressure reductions and a low major adverse event rate 6 months following treatment with the Vessix system. Office blood pressure measurements and safety monitoring continues through 2 years post-treatment.

METHODS The REDUCE-HTN trial is a prospective, multicenter, single-arm study. Patients were required to have an office-based systolic blood pressure ≥160 mmHg despite treatment with ≥3 antihypertensive medications at maximally tolerated doses.

RESULTS Among enrolled patients (N=146), mean baseline office blood pressure was 182.4±18.4/100.1±14.0 mmHg and ambulatory blood pressure was 152.9±15.2/87.5±13.3 mmHg. Among 94 patients with 18 month data, mean office blood pressure was reduced to 157.2±24.6/86.9±14.8 mmHg; a reduction of 27.1±20.4/11.2±11.4 mmHg (P<.0001). Eighty percent of those (75/94) responded to treatment with a reduction in office systolic blood pressure ≥10 mmHg at 18 months. The rate of procedure-related serious adverse events was 5.6% at 6 months, with no new procedure- or device-related serious adverse events reported between 6 and 18 months of follow-up. Final 2-year efficacy and safety data will be available at the time of presentation.

CONCLUSIONS Eighteen-month data available to date from the REDUCE-HTN study support the safety and efficacy of renal denervation with the Vessix system to treat resistant hypertension, with potential for sustained blood pressure reductions through 2 years.

CATEGORIES ENDOVASCULAR: Hypertension Therapies and Renal Denervation

KEYWORDS Clinical Trial, Hypertension, Renal denervation

TCT-765

Renal Denervation in the Treatment of Resistant Hypertension: A Meta-Analysis of Eight Randomized Controlled Trials

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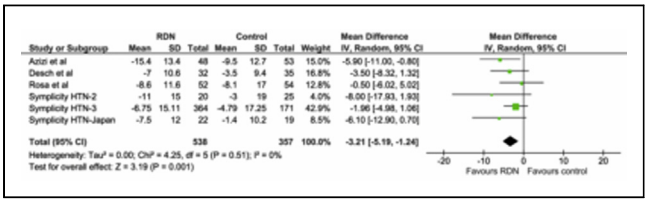
BACKGROUND Renal sympathetic denervation (RDN) has been introduced as a possible treatment for resistant hypertension (RH); however, the largest trial to date has shown little benefit. Our aim was to compare renal denervation versus pharmacological therapy in patients with resistant hypertension in eight trials.

METHODS We conducted a meta-analysis of prospective trials which randomized patients with resistant hypertension to renal denervation or pharmacological antihypertensive treatment alone and reported the pre-specified outcomes. Mantel Haenszel relative risks and mean differences were calculated using random effect models.

RESULTS Eight trials (N=1011) met the inclusion criteria. At 6 months RDN was associated with greater reduction in 24-hour systolic blood pressure (SBP) (mean difference -3.21; 95% CI -5.19, -1.24; P=0.001), and 24-hour diastolic blood pressure (DBP) (mean difference -1.60; 95% CI -2.76, -0.44; P=0.007). RDN was also associated with a decrease in the number of antihypertensive medications compared to the control arm (mean difference -0.32; 95% CI -0.52, -0.11; P=0.002). The mean difference in change between RDN and control was -7.69 mm Hg for office SBP (P=0.18), and -4.54 mm Hg for DBP (P=0.009) favoring RDN. Sensitivity analysis including trials with homogenous antihypertensive medical treatment protocol among the RDN and controls showed significant reductions in office systolic and diastolic BP at 6 months favoring RDN (mean difference -14.6; 95% CI -26.28, -2.92; P=0.01), (mean difference -6.06; 95% CI -9.60, -2.53; P<0.001), respectively. There was no significant difference in terms of heart rate, kidney function, myocardial infraction, stroke, or hypertensive emergency.



CONCLUSIONS RDN is associated with significant 24-hour ambulatory and office based reduction in both systolic and diastolic blood pressure compared to pharmacological treatment alone. Renal denervation is safe and may have a potential role as an adjunct treatment in patients with resistant hypertension.

CATEGORIES ENDOVASCULAR: Hypertension Therapies and Renal Denervation

KEYWORDS Ambulatory blood pressure monitoring (ABPM), Renal Denervation, Resistant hypertension

TCT-766

Sub-acute Safety and Efficacy Evaluation of a Single versus Double Treatment Cycles of a Monopolar Radiofrequency Catheter-Based Renal Nerve Ablation and its Chronic Evolution in a Large Animal Model

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BACKGROUND Transcatheter renal denervation (RDN) therapy has emerged as a therapeutic option for patients diagnosed hypertension resistant to pharmacologic therapy. We aimed to evaluate the effects of radiofrequency treatment (RF) delivered by the Terumo Iberis™ catheter in a large animal model. Additionally, as a secondary end point, we aimed to determine the safety implications of delivery of one cycle versus two cycles of RF ablations.

METHODS 22 domestic swine were enrolled. 18 animals underwent RDN, performed bilaterally; 4 remained untreated as naïve controls for norepinephrine levels (NE) only. Renal arteries were randomized to receive a single cycle of 120 seconds (n=24) treatment and were followed for 7, 30 and 90 days. 8 renal arteries received 2 treatment cycles (240 seconds total) and were followed for 7 days only. 3 arteries were untreated. Renal cortical samples from the single-cycle treatment group were harvested for NE evaluation at each time point. All renal arteries were harvested for histology and immunohistochemical (IHC) evaluation.

RESULTS All renal arteries were suitable for RF therapy by angiography. The characteristic "notches" post-RF were observed in all treated arteries. At follow up, all arteries demonstrated no luminal obstruction with a TIMI 3 flow. The NE assay showed a 70% decrease in NE levels (76.68±57.87 ng/g) at 7 days post RDN, 81% significant decrease at 30 days (49.05±45.81 ng/g), and 51% decrease at 90 days (12.7±73.2 ng/g) compared to control (254.1±54.1 ng/g). Histologically, the thermal effect in the perivascular tissue extended from an average of 40% to a complete (100%) circumferential involvement with a depth reaching up to 8 mm. The primary histological and IHC feature at 7 days was nerve necrosis with consequent nerve atrophy distal to the RF treated level; the arterial wall showed complete re-endothelialization and hyalinization of the media (thermal coagulation necrosis). At 30 days, necrosis was no longer prominent and was replaced by healing changes of fibrosis. Neuromatous regeneration was apparent at 30 days at RF treated levels, a change characterized by disorganized sprouting of neuroid fibers within the thickened perineurium. At 90 days these features progressed to become more